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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,167	04/10/2006	Timothy Fong	28578/US/2 (47451-105046)	5766

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EXAMINER	
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ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,167	FONG ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

In the Sequence Listing filed November 13, 2008, for SEQ ID NO:1, the definitions of the residues at positions 2-4 and 6-8 are unclear. In the MISC FEATURE section for these references, the text implies that the aromatic amino acid has to have from 5-6 carbon atoms, which would exclude the naturally occurring amino acids Phe, Tyr, His, and Trp from the definition. Further, the preferred embodiment in this section, i.e. "any amino acid other than a polar aliphatic amino acid", is broader than the initially recited definition, because the preferred embodiments embrace non-polar aliphatic amino acids having other than 5-6 carbon atoms. For analogous reasons, the definitions of the residues at positions 3-4 and 6-8 of SEQ ID NO:2 are also unclear.

The MISC FEATURE section for residues 6-8 in SEQ ID NO:2 is repeated.

SEQ ID NO:28, as defined in the Sequence Listing filed November 13, 2008, and as inserted into paragraphs [0059] and [0060] of the specification and into claims 2 and 16, comprises new matter. The definitions of residues 2-4 and 6-8 recite that these amino acids can be any D-stereoisomer amino acid. However, paragraph [0060] of the specification as originally filed recites only that the norleucine, arginine, and tyrosine residues present in SEQ ID NO:28 can be the D-stereoisomer. Accordingly, the definition of these residues in the Sequence Listing is broader than the original disclosure.

Applicant must provide a substitute computer readable form (CRF) copy of the Sequence Listing, a substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b).

The computer-readable form of the Sequence Listing filed November 13, 2008 was approved by STIC for matters of form.

2. The disclosure is objected to because of the following informalities: At paragraph [0066] as amended on October 30, 2007, line 5, SEQ ID NOS must be inserted after (Gly)n for n=4-7. See 37 CFR 1.821(d). Amended paragraph [0092] contains an acceptable format for these sequences. Appropriate correction is required.

3. The amendment filed November 13, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: SEQ ID NO:28 as inserted into paragraphs [0059] and [0060] of the specification and as defined in the Sequence Listing filed November 13, 2008 contains new matter. The definitions of residues 2-4 and 6-8 recite that these amino acids can be any D-stereoisomer amino acid. However, paragraph [0060] of the specification as originally filed recites only that the norleucine, arginine, and tyrosine residues present in SEQ ID NO:28 can be the D-stereoisomer. The definition of these residues in the Sequence Listing is broader than the original disclosure, and therefore contains new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 16-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. SEQ ID NO:28 as defined in the Sequence Listing filed November 13, 2008 and as recited in claims 2 and 16 of the claims is not supported by the original disclosure of the invention. As originally disclosed, e.g., at paragraph [0060] of the specification and in originally filed claims 2 and 16, SEQ ID NO:28 must have the amino acid sequence Arg-nL-nL-nL-Arg-nL-nL-nL-Gly-Tyr, in which any residue other than Gly can be the D-stereoisomer. However, the definition of the sequence in the Sequence Listing filed November 13, 2008 broadens the definition so that the amino acid residues at positions 2-4 and 6-8 can be any D-stereoisomer amino acid. Applicants have not indicated where the original disclosure of the invention supports the new claim language.

5. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Applicants claim a method of administering "an RDP58 oligopeptide". Because the terminology forms part of the claim, it is essential material. The claim terminology appears to be defined in paragraphs [0052] and [0061] of the specification, which refer to WO 98/46633 (which was published based upon PCT/US98/07231) and U.S. Patent Applications 09/028,083 and 08/838,916. However, these references are not U.S. patents or U.S. patent application publications, and incorporation by reference of essential material using such references is not permitted. For U.S. Patent Application 09/028,083, this objection can be overcome by replacement of the application number with its patent number, i.e. U.S. Patent No. 6,696,545.

6. Claims 1-9 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble to claim 1 recites "A method of treating interstitial cystitis", and "treating" is defined at paragraph [0047] as including prophylaxis, including administration to subjects prior to the onset of symptoms or other manifestations. However, claim 1, line 2, recites "an affected subject", and therefore it is unclear if the claim requires the treatment of a subject who already has the disease. Claim 18 recites that all of the amino acids of the oligopeptide are the D-isomer; however, the oligopeptide requires the presence of a glycine residue, which has neither a D-isomer nor an L-isomer.

7. Instant claims 1-20 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/470,839 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose, e.g., the treatment of interstitial cystitis.

Instant claims 1-20 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/426,684 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose, e.g., the administration of "an RDP58 oligopeptide" in general; does not disclose oligopeptides consisting of SEQ ID NO:28 in which residues 2-4 and 6-8 can be D-stereoisomers of any amino acid, including polar aliphatic amino acids; does not disclose treating acute interstitial cystitis or chronic interstitial cystitis; does not disclose ameliorating a manifestation of interstitial cystitis which is NGF expression or degradation of urine/blood barrier (compare paragraph [0078], where these manifestations are not mentioned); and does not disclose ameliorating a manifestation of interstitial cystitis which is TNF-α expression (compare paragraph [0011], which states that TNF-α concentrations are not increased in patients with interstitial cystitis). With respect to the instant claim terminology "an RDP58 oligopeptide", note that the instant application appears to define the term in paragraphs [0052] and [0061] of the specification at least in part by reference to WO 98/46633 (which was published based upon PCT/US98/07231) and U.S. Patent Applications 09/028,083 and 08/838,916. However, the provisional application's broadest description of active agents, at paragraph [0023], refers only to U.S. Patent Applications 09/028,083 and 08/838,916. While WO 98/46633 claims priority based upon the two U.S. Patent Applications, there is no requirement and there is no presumption that the disclosure of WO Patent Application is the same as the disclosure of the applications upon which it claims priority. Accordingly, because the definition of "an RDP58 oligopeptide" in the instant application appears to be broader than the description of the active agents in the provisional application (because more references are

cited in the definition than in the provisional application), claims in which the term appears are not deemed to be supported by the disclosure of the provisional application.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 1 and 7-15 are rejected under 35 U.S.C. 102(a) as being anticipated by the Gonzalez et al abstract (J. Urology, Vol. 169, pages 68-69). The Gonzalez et al article teaches treating acute cystitis in a mouse model by administering RDP58 into the bladder by instillation. RDP58 is a peptide which inhibits TNFα in vivo. Mast cell counts and edema are decreased in the mice treated with RDP58. Because the same active agent is being administered to the same subject according to the same method steps, inherently the same manifestations of interstitial cystitis, e.g., histamine release, Substance P expression, NGF expression, TNF-α expression, and degradation of urine/blood barrier, will be ameliorated in the method of the Gonzalez et al abstract to the same extent claimed by Applicants. With respect to instant claim 9, note that Applicants have defined "treating" at paragraph [0047] of the specification as including prophylaxis. Because the same active agent is being administered to the same subject according to the same method steps, inherently chronic interstitial cystitis will be prevented in the method of the Gonzalez et al abstract to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of the Gonzalez et al abstract and Applicants' claimed method to shift the burden to Applicants to provide evidence that the claimed method is unobviously different than the method of the Gonzalez et al abstract.

The Gonzalez et al abstract is prior art against the instant claims under 35 U.S.C. 102(a) because the Gonzalez et al abstract was published prior to the effective filing date of the instant claims (see section 7 above), and because the Gonzalez et al abstract contains two additional authors in comparison to the inventorship of the instant application, i.e. is "by others".

10. Claims 2-6 and 16-20 are rejected under 35 U.S.C. 102(a) as being anticipated by the Gonzalez et al abstract (J. Urology, Vol. 169, pages 68-69) as applied against claims 1 and 7-15 above, and further in view of Gamache (U.S. Patent No. 7,026,296). The Gonzalez et al abstract teaches the administration of RDP58, but does not teach the amino acid sequence for this peptide. Gamache teaches that the amino acid sequence of RDP58 is (D)Arginyl-(D)Norleucyl-(D)Norleucyl-(D)Arginyl-(D)Norleucyl-(D)Norleucyl- -(D)Norleucyl-Glycine-(D)Tyrosine-amide, acetate salt. See column 3, lines 26-29.

11. Claims 1, 3, 4, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 98/46633. The WO Patent Application '633 teaches administering RDP58 oligopeptides to subjects, e.g., intraperitoneally. The peptides are synthesized as amides and converted to acetate salts. See, e.g., page 27; page 28, lines 7-8; and Examples 3 and 9. Note that Applicants appear to define "RDP58 oligopeptide" at least in part through incorporation by reference to the WO Patent Application '633 (see paragraphs [0052] and [0061] of Applicants' specification), and therefore the peptides disclosed in the WO Patent Application '633 are RDP58 oligopeptides. Note also that Applicants appear to define "treating" as including prophylaxis (see paragraph [0047] of the specification, but also see the above rejection under 35 U.S.C. 112, second paragraph). Finally, Applicants disclose intraperitoneal administration to be a useful method of administering their RDP58 oligopeptides (see paragraph

[0128]). Because the same peptides are administered to the same subjects according to the same method steps, inherently interstitial cystitis will be prevented in the method of the WO Patent Application '633 to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of the WO Patent Application '633 and Applicants' claimed method to shift the burden to Applicants to provide evidence that the claimed method is unobviously different than the method of the WO Patent Application '633.

12. Keay et al (U.S. Patent Application Publication 2001/0000783) was cited in the International Search Report for corresponding application PCT/US2003/37043.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
January 16, 2009